IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8423

Bartle, C.J. March 10, 2010

Virginia McClure ("Ms. McClure" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael S. Mancina, M.D., F.A.C.C. As we previously have noted, Dr. Mancina is no stranger to this litigation. See Pretrial Order ("PTO") No. 6280 at 3 (May 19, 2006). Based on an echocardiogram dated November 17, 2001, Dr. Mancina attested in Part II of Ms. McClure's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $449,381.[3]

In the report of claimant's echocardiogram, Dr. Mancina stated that "[t]here is moderate mitral valve regurgitation by Phen-Fen criteria with 37% of the left atrium occupied by regurgitant flow during systole." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2002, the Trust notified Ms. McClure that her claim had been selected for audit.[4] Claimant subsequently

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3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

4. Although the Trust issued a favorable Tentative Determination Letter in August, 2002, under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; PTO No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's level of mitral regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

advised the Trust that she did not intend to submit additional medical information in support of her claim. The Trust then forwarded the claim for review by Keith B. Churchwell, M.D., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Mancina's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Churchwell explained that "[t]here is significant overestimation of the area of the regurgitant fraction traced in the [left atrium.] There is mild mitral regurgitation present in comparison to [left atrium] size/area."

Based on the auditing cardiologist's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. McClure's claim. Pursuant to the Audit Policies and Procedures, claimant disputed this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.[5] The Trust then applied to the court for issuance of an Order to show cause why Ms. McClure's claim should be paid. On April 8, 2003, we issued an Order to show cause and referred the

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5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. McClure's claim.

matter to the Special Master for further proceedings. See PTO No. 2826 (Apr. 8, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 19, 2003, and claimant submitted a sur-reply on July 7, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. § VI.D.

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. McClure submitted an expert opinion by Frank E. Silvestry, M.D. Relying on two still frames from claimant's echocardiogram, Dr. Silvestry confirmed the attesting physician's finding of moderate mitral regurgitation.[7] Dr. Silvestry explained that:

> I measured the maximum regurgitant jet and measured its area using EchoAnalysis software. The jet I traced is an aliased Doppler jet emanating from the mitral valve in systole. The degree of mitral regurgitation is 22.0% with the maximal jet drawn shown (See Exhibit A-1). My tracing clearly shows that the mitral regurgitant jet area is 4.20 cm2, and the left atrial area is 18.11 cm2 (as shown in my tracing of the left atrial area which is attached as Exhibit A-2), and that Ms. McClure has moderate (22.0%) mitral regurgitation as that term is defined in the Green Form.

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7. In Dr. Silvestry's report, he states that "[t]he opinions rendered in this report are based on a reasonable degree of medical certainty, and are intended to provide legal consultation for forensic expert evaluation only. This report is not intended to provide medical opinions regarding treatment of the identified patient. No one should rely on the opinions expressed in this report for the diagnosis, prognosis or treatment of their medical condition. The interpretation above does not constitute a doctor patient relationship with the above client."

> As per Green Form appendix endnotes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The auditing cardiologist does not contest the presence of mitral regurgitation. The auditing cardiologist may be expressing his or her qualitative opinion of the degree of mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree that is clearly substantiated by the echocardiogram, and my independent measurements.

In addition, claimant argues that: (1) the requisite level of regurgitation need be based only on the maximum regurgitant jet[8]; (2) the auditing cardiologist's conclusions should be given no weight because he did not explain his findings, and thus, "the Trust has not met its burden to deny payment of this claim"; and (3) the auditing cardiologist was required, under the Settlement Agreement, to provide a specific measurement as to the level of regurgitation.[9]

In response, the Trust argues that there is no reasonable medical basis for Ms. McClure's claim because the auditing cardiologist determined that the attesting physician overtraced the regurgitant jet area. The Trust further contends that claimant's experts improperly relied on a single regurgitant

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8. Although claimant asserts that "[t]he mitral regurgitation was not based on a single frame analysis but was seen in multiple views," there is no support for this assertion, which directly contradicts Dr. Silvestry's statement, in the Show Cause Record.

9. Ms. McClure also asserts that the issue of reasonable medical basis should be controlled by the opinion of Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher decision as controlling or persuasive. See, e.g., PTO No. 6275 at 9 (May 19, 2006).

jet to support their finding of moderate mitral regurgitation. The Trust also avers that the auditing cardiologist complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. In addition, the Trust asserts that claimant cannot meet her burden simply by proffering additional opinions. Finally, the Trust argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts.

In her sur-reply, Ms. McClure argues that Rule 26(a)(2) is not applicable to these proceedings. We agree. See PTO No. 6997 at 11-12 n.13 (Feb. 26, 2007).

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram was representative of only mild mitral regurgitation. In particular, Dr. Burke stated that:

> In this echocardiogram of November 17, 2001, I found technical limitation that involved overtracing of the regurgitant jet area in all 5 of the "freeze frame" shots on the tape as well as the exhibit provided. In the left atrial area provided by the second reviewing cardiologist, Frank Silvestry, M.D., I found the left atrial area to be undertraced.
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> My overall view of the representative level of regurgitation in this study is that the patient has mild mitral regurgitation.

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In the apical long axis view, I counted 17 beats with color flow Doppler imaging that were interpretable for [mitral regurgitation] assessment. My overall view of the representative level of regurgitation in this echocardiogram is mild, as the majority of the beats showed trace or mild [mitral regurgitation]. Limiting the review to the five beats that had the most regurgitation, on average, I calculated a RJA to LAA ratio of 24.6% - in the range for moderate. I also note that the gain setting for the color flow Doppler was set high, although not out of an acceptable range.

The 5 beats in the apical long axis view that, on average, demonstrate moderate [mitral regurgitation] as assessed by RJA/LAA ratio, were not, however, consistent with the findings of trace to mild regurgitation noted on the other beats of this view as well as the beats on all the other views.

In the apical 4-chamber view, I counted 33 beats with color flow Doppler imaging that were interpretable for [mitral regurgitation] assessment including "freeze frame" shots. All beats showed trace or mild [mitral regurgitation]. On average I calculated an overall RJA to LAA ratio of 13.2% - range for mild [mitral regurgitation].

* * *

In conclusion, my assessment is that this patient has mild and not moderate mitral regurgitation. The few beats with the largest regurgitant jet area in the apical long axis view would reach a value in the range for moderate mitral regurgitation. Yet, these few beats are not consistent with nor representative of the degree of regurgitation noted on the remainder of the tape. I do not believe, therefore, there is a reasonable medical basis for the Attesting Physician's answer to the Green Form Question C.3.a. that the echocardiogram in question demonstrates moderate mitral regurgitation.

In response to the Technical Advisor Report, claimant argues that Dr. Burke's finding that moderate mitral regurgitation existed on several frames of her echocardiogram is sufficient to establish a reasonable medical basis for her attesting physician's findings.[10] Claimant also contends that Dr. Burke's finding that Ms. McClure's echocardiogram demonstrated only mild mitral regurgitation is not in compliance with the Settlement Agreement because a claimant is not required to demonstrate the requisite level of regurgitation in all apical views.[11]

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately rebut or address the deficiencies noted by both the auditing cardiologist and the Technical Advisor. Claimant does not rebut the auditing cardiologist's conclusion that "[t]here is significant overestimation of the area of the regurgitant fraction traced in the [left atrium]." Nor does claimant challenge the Technical

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10. Claimant also mentions that her reviewing cardiologist, Dr. Silvestry, is a member of the Medical Review Coordinating Committee ("MRCC") established under the Seventh Amendment to the Settlement Agreement and that he uses Echo Analysis software, a computer program that measures the area of regurgitation. As claimant fails to explain how either Dr. Silvestry's participation on the MRCC or his use of Echo Analysis software establishes a reasonable medical basis for her claim, these matters are irrelevant to the disposition of this claim.

11. In support, Ms. McClure submitted a partial transcript of testimony from John Dent, M.D., the Trust's expert during the September, 2002 hearings that ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002).

Advisor's finding that Ms. McClure's echocardiogram had "technical limitation that involved overtracing of the regurgitant jet area in all 5 of the 'freeze frame' shots on the tape ...." There simply is no reasonable medical basis for any conclusion of a cardiologist that is based on improper tracings, or any other conduct that results in an inflated level of regurgitation. As we previously have found, conduct "beyond the bounds of medical reason" can include overtracing the amount of a claimant's regurgitation and characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation. See PTO No. 2640 at 12, 15, 22.

We also disagree with claimant's assertion that her claim is payable as the Trust did not meet its burden to deny payment of her claim. To the contrary, the Audit Policies and Procedures state, in pertinent part, that:

> For audits based, in whole or in part, on the grounds that no reasonable medical basis exists for specific answer(s) to the Audit Question(s), the Claimant shall have the burden of proving that there was a reasonable medical basis to support the material representation(s) made by the Attesting Physician in answering the Audit Question(s).

Audit Policies and Procedures § VI.D. As Ms. McClure failed to address adequately the auditing cardiologist's and Technical Advisor's findings that she had only mild mitral regurgitation, she has not met her burden in establishing a reasonable medical basis for her claim.

In addition, we reject claimant's assertion that she may recover Matrix Benefits by the use of a single maximum measurement of the level of mitral regurgitation. In support, claimant proffered a letter from Dr. Silvestry, who concluded, based on a single measurement of "the maximum regurgitant jet," that claimant had moderate mitral regurgitation. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram."[12] PTO No. 6997 at 11. "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

Moreover, we previously have stated that "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 at 7 (Jan. 26, 2007) (quoting PTO No. 2640 at 9). As claimant has not established that the "maximum regurgitant jet" offered in support of her claim is

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12. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. "Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition." PTO No. 6997 at 11 n.12.

representative of her level of mitral regurgitation, claimant has failed to establish a reasonable medical basis for her claim. This is especially true where, as here, the Technical Advisor concluded that, while certain beats on claimant's echocardiogram demonstrated moderate mitral regurgitation, they were not representative of her level of regurgitation throughout the echocardiogram, which the Technical Advisor found to be only mild. Rather than rebutting these specific determinations made by the Technical Advisor, claimant relies solely on an erroneous interpretation of the Settlement Agreement.[13] On this basis as well, claimant has failed to meet her burden in establishing a reasonable medical basis for her claim.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we also explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be

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13. For this reason as well, we reject claimant's argument that the Technical Advisor applied an improper standard in determining that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. McClure's claim for Matrix Benefits.